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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,733	07/20/2005	Motoaki Kamachi	Q89240	5404

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EXAMINER

LILLING, HERBERT J

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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08/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,733

Applicant(s)

KAMACHI ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Receipt is acknowledged of a preliminary amendment filed July 20, 2005, two prior art information disclosure statements filed July 20, 2005 and July 13, 2006 and a certified copy of foreign priority filed July 20, 2005 for this application which is a 371 of PCT/JP04/00500 filed January 21, 2004 which claims benefit to two Japanese documents 2003-13762 filed January 22, 2003 and 2003-94881 filed March 31, 2003.

Applicant is requested to amend the specification to includes the above continuing data after the Title of the Invention.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1 based on the current record as noted in the search report.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to a method for acyltransferase reaction in which an acyl group of acyl coenzyme A (acyl CoA) is transferred characterized in that the reaction is carried out by production and/or reproduction of acyl coenzyme A from coenzyme A in a reaction system by a chemical thioester exchange reaction with an acyl group donor which is an acyl ester of a thiol compound, classified in class 435, subclass 92.
- II. Claims 21-22, drawn to a production process of a sphingoid base using the acyltransferase reaction wherein an acyl group receptor is serine and/or a derivative, classified in class 435, subclass 41+ depending upon the reactants.
- III. Claim 23, drawn to a process for preparing a ceramide using a sphingosine N-acyl transferase, classified in Class 435, subclass 129.

IV. Claims 24-27, drawn to a process for the preparation of macromolecular polyesters wherein an acyltransferase is a macromolecular polymerization enzyme and a macromolecular compound is synthesized in a reaction in which an acyl group donor, acyl group receptor, coenzyme A and acyltransferase are contained in the reaction system at the same time, an acyl group of the acyl group donor is transferred to coenzyme A by a chemical thioester exchange reaction to give an acyl coenzyme A and an acyl group of the acyl coenzyme A is transferred to the acyl group receptor, classified in Class 435, subclass depending upon the macromolecular compound produced which includes subclasses 134 and 135.

Each of the above four groups of claims would involve a different search and examination which examination would be a serious burden for this Examiner.

This Examiner has provided reasons why a serious burden exists in this application drawn to the four sets of claims based on the following facts:

A. There is a serious burden as indicated by the fact each of the groups for each of the inventions has separate classification as noted above which is sufficient reasons and prima facie evidence of a serious burden to examine all of the above inventions drawn to different separate classification as defined in MPEP 808.02: for the extreme burdensome search to examine all of the above inventions.

(A) Separate classification thereof : This shows that each invention has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search.

(B) **A different field of search**: Where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other invention(s) (e.g., searching different classes /subclasses or electronic resources, or employing different search queries, a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to the type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

The search and examination of the multiple inventions would be a serious burden on this Examiner in view of the additional inventions that **involves different computer searches for each of the different inventions which also involves different substrates to prepare different compounds.**

The M.P.E.P. indicates that a serious burden may be established on a different field of search if it is necessary to search for one of the inventions in a manner not likely to result in finding art pertinent to the other invention which includes (a) searching different classes and different subclasses; searching different electronic resources or employing different search queries.

However, if Applicant states on the record the statement with the express admission "that the inventions are obvious over each other within the meaning of 35 U.S.C. 103"" and provide the reasons for the obviousness, this Examiner will withdraw the restriction requirement in accordance with the MPEP 803.

3. This application contains claims directed to the following patentably distinct species:

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A. Whereby the acyltransferase is selected from the following:

- a. serine C-palmitoyl transferase,
- b. sphingosine N-acyl transferase,
- c. macromolecular polymerization enzyme,

if elected further election:

- c1. polyhydroxy alkanoate synthase,
- c2. other-please specify.
- d. other-please specify.

B. Whereby the reaction is carried out by:

- i. production of acyl coenzyme A ,
- ii. reproduction of acyl coenzyme A.

C. Whereby the acyl ester of a thiol compound is selected from

- a. non-aromatic thiol,
- b. aromatic thiol
 - ba. thiophenol,
 - bb. methylthiophenol,
 - bc. chlorothiophenol,
 - bd. 2-mercaptothiazole,
 - be. 2-mercaptoimidazole,
 - bf. 2-mercaptotriazole,
 - bg. 2-mercaptobenzothiazole,

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- bh. 2-mercaptobenzimidazole,
- bi. 2-mercaptopyridine,
- bj. Mixtures of above,
- bk. Other(s)-please specify.

D. Whereby the acyl group receptor is:

- 1. amino acid,

If elected, further election of species:

- 1a. serine,
- 1b. mixtures of above- please specify,
- 1c. other(s)-please specify the compound(s).

- 2. amino acid derivative

If elected:

- 2a. sphingosine
- 2b. other,
- 2c. mixture(s)-please specify the compounds
within the mixture(s).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

However, if Applicant states on the record the statement with the express admission “that the species are obvious over each other within the meaning of 35 U.S.C. 103” and provide the reasons for the obviousness, this Examiner will withdraw the election requirement.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species from each of the above paragraph 3 which includes: A [a. or b. or c or d] whereby if Ac is elected there is a further election of [Ac1 or Ac2]; B [i. or ii.] ; C [a. or b.-which if elected further one species from ba to bk] and D [1 or 2 with a further election if species D1 is selected [a, b or c] or if species D2 is selected [a. b. or c] **and** an election of one of the inventions from I-IV to be examined even though the requirement be traversed (37 CFR 1.143) and **(ii) identification of the claims encompassing the elected invention.**

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Please note that Applicant is required to identify all claims which encompass the elected invention pertaining to the elected species commensurate in scope with the elected invention.

Applicant is kindly requested to contact this Examiner for any assistance in the identification of the claims which encompass the identified elected claims.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

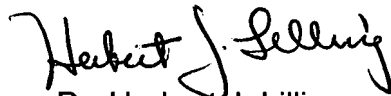
6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
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July 16, 2007



Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657

RAW SEQUENCE LISTING

**The Biotechnology Systems Branch of the Scientific and Technical
Information Center (STIC) no errors detected.**

Application Serial Number: 10/542,733
Source: PCT
Date Processed by STIC: 07/28/2005

ENTERED